IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DIANE WILLIAMS, et al., Plaintiffs	:	CIVIL ACTION
v.	:	NO. 06-5361
CYBERONICS, INC., Defendant	:	

September _10__, 2009 **Anita B. Brody, J.**

MEMORANDUM

This case involves a medical device that treats epilepsy and depression by electronically stimulating the vagus nerve in a patient's neck. Alleging that this device malfunctioned, Diane Williams, Keith Williams, and Audrey Knight (collectively, "Plaintiffs") have sued the manufacturer, Cyberonics, Inc. ("Cyberonics").

In the Third Amended Complaint, Plaintiffs assert the following claims: strict liability for a manufacturing defect (Count I), breach of warranty (Count II), fraudulent misrepresentation (Count III), and negligent misrepresentation (Count IV).

I. BACKGROUND

The VNS Therapy System™ ("VNS System") manufactured by Cyberonics consists of a small generator implanted in a patient's chest below the clavicle and a thin, flexible lead wire connecting the generator to the left vagus nerve, located in the neck. The generator sends periodic electrical stimuli through the lead to the vagus nerve, which in turn stimulates the brain. The VNS System is designed to deliver an electrical pulse every five minutes. The pulse itself

lasts for 30 seconds. After the device is implanted, a physician programs the device to provide the appropriate level of stimulation. Patients undergoing VNS therapy wear a magnetic bracelet, which can be used to temporarily deactivate the generator.

The VNS System is a Class III medical device approved by the U.S. Food and Drug Administration ("FDA"). The FDA separates medical devices into three categories, based on the level of risk that they pose. Class III devices, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, receive the most oversight from the FDA. Riegel v. Medtronic, Inc., 128 S.Ct. 999, 1003 (2008). The Medical Device Amendments of 1976, 21 U.S.C. §§ 360c *et seq.* ("Medical Device Amendments"), require new Class III devices to undergo a rigorous process known as premarket approval. Premarket approval includes an in-depth review of scientific and clinical data. The FDA spends an average of 1,200 hours reviewing each application. Riegel, 128 S.Ct. at 1004. It is required to weigh "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). The FDA may approve devices that pose significant risks to the patient if they also offer large benefits. Riegel, 128 S.Ct. at 1004. After a device has been approved, the manufacturer is forbidden to change design specifications that affect safety or effectiveness without FDA permission. Id. at 1005 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

The VNS System was evaluated twice by the FDA through the premarket approval process. Based on its evaluations, the FDA approved the VNS System for treating epilepsy in 1997 and for treatment resistant depression in 2005. The claims at issue in this action relate to the use of the VNS System for treatment resistant depression.

Audrey Knight ("Knight"), a Florida citizen, underwent the VNS System surgical implantation in Orlando, Florida on March 23, 2006. Knight testified that VNS therapy did not help her symptoms and that she felt pain from the device. Eight months after the implantation, she felt the VNS System deliver a series of powerful electric shocks. These severe shocks continued until Knight was forced to tape a magnet over the device, effectively switching off the VNS System until it could be surgically explanted. Dr. Eric Trumble observed one of the severe shocks and Knight's "severe adverse reaction." Although he was unable to determine what caused the severe shock, he noted that "it was clearly not as a result of how the device had been surgically implanted." On March 15, 2007, Knight's VNS System was explanted. A Cyberonics product analysis of the VNS System after it was explanted revealed no evidence of any malfunction and determined that the device was functioning as designed.

Diane Williams ("Williams"), a Pennsylvania citizen, underwent the VNS System surgical implantation in York, Pennsylvania on November 21, 2005.[1] Four months after Williams underwent implantation, the device had no effect on her depression and Williams reported that she was no longer able to feel an electrical pulse from the VNS System. On April 28, 2006, Williams underwent an exploratory surgery to determine if there was a problem with the device. Dr. Joel Winer, a neurosurgeon who performed the surgery, told Williams that he did not see anything wrong with the device. During the procedure, Dr. Winer removed the generator, checked the battery, irrigated the site, and reinserted the generator. After the procedure,

[1] Cyberonics is a corporation organized and existing under the laws of the State of Texas, with its principal place of business in Texas. Plaintiffs allege damages in excess of $75,000. Jurisdiction is proper pursuant to 28 U.S.C. § 1332(a).

Williams was able to feel stimulation. However, in July 2006, Williams again reported that she no longer felt the electrical pulses. Her doctors adjusted the device output so that no stimulation was provided, and the device was explanted on July 16, 2008. Cyberonics conducted a product analysis after the device was explanted, which revealed no product related anomalies and established that the device was functioning as designed.

Williams' insurance company did not pay for the implantation or the second surgery. It did pay for the explantation. Williams testified that she did not personally manage the insurance claims, and that her husband, Keith Williams ("Mr. Williams"), took primary responsibility for dealing with Cyberonics and the insurance company on insurance related issues.

Mr. Williams testified that before the first surgery the insurance company told him it would not pay for the VNS System because it was experimental and investigational. He then spoke with a Cyberonics case manager, who said Cyberonics would help him get the VNS System approved through an appeal process to the Office of Personnel Management. The case manager told him "that they very rarely had any problem with [the Office of Personnel Management] denying approval" and that she was "pretty sure" it would be approved. The Williams decided to proceed with the implant of the VNS System. When asked why they decided to seek treatment with the VNS System implant even after the insurance company told him it would not pay, Mr. Williams responded that he felt it was necessary to save his wife's life. Mr. Williams testified that Cyberonics did not promise him that his insurance company would pay for the VNS System. He also testified that he understood that approval for payment was at the Office of Personnel Management's discretion.

II. SUMMARY JUDGMENT STANDARD

Summary judgment will be granted "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). There is a "genuine" issue of material fact if the evidence would permit a reasonable jury to find for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The "mere existence of a scintilla of evidence" is insufficient. Id. at 252.

The moving party must make an initial showing that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The non-movant must then "make a showing sufficient to establish the existence of [every] element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322. The non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). In determining whether the non-moving party has established each element of its case, the court must draw all reasonable inferences in the non-moving party's favor. Id. at 587.

III. DISCUSSION

In their Third Amended Complaint, Plaintiffs assert claims of strict liability for a manufacturing defect (Count I), breach of warranty (Count II), fraudulent misrepresentation (Count III), and negligent misrepresentation (Count IV).

A. Strict Liability for a Manufacturing Defect (Count I) and Breach of Warranty (Count II)

1. Preemption

The Medical Device Amendments impose a rigorous regime of premarket approval for Class III medical devices such as the VNS System. The Medical Device Amendments also provide a preemption clause:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Supreme Court recently addressed the Medical Device Amendments' preemption clause in Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008), a case involving a Class III catheter approved by the FDA through the premarket approval process. Charles Riegel ("Riegel"), one of the plaintiffs, underwent a procedure where his doctor inserted the Evergreen Balloon Catheter manufactured by Medtronic, Inc. ("Medtronic") into his coronary artery. The doctor inflated the catheter beyond its rated burst pressure, and the catheter ruptured while it was inside Riegel's coronary artery. Riegel sued Medtronic alleging that the catheter was designed, labeled, and manufactured defectively. The Supreme Court held that Riegel's strict liability claim, breach of implied warranty claim, and all of his negligence claims, except for a negligent manufacturing claim, were preempted by the premarket approval of the catheter by the FDA. The Supreme Court established a two-part test for determining whether a claim is preempted. First, a court must determine whether the Federal Government has established requirements applicable to the

medical device. Riegel, 128 S.Ct. at 1006. Second, a court must determine whether the state common-law claims impose requirements that are "different from, or in addition to" those imposed by federal law. Id. Plaintiffs concede that the FDA has established requirements applicable to the VNS System, so I need only address the second part of the test.

Riegel allows products liability and implied breach of warranty claims against a manufacturer of a Class III medical device only where the claims are "premised on a violation of FDA regulations" relating to the device. Id. at 1011. Riegel is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass on those two claims. No state common-law claim can survive if it allows a claimant to proceed without showing a departure from federal standards. There simply is no wiggle room to find otherwise.

To avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards. The plaintiffs in this action have failed to provide any evidence of such a departure.

2. Choice of Law

When hearing a case on diversity jurisdiction, federal courts apply the choice of law rules of the forum state. Peco Energy Co. v. Boden, 64 F.3d 852, 855 (3d Cir. 1995). Pennsylvania law provides that "the place having the most interest in the problem and which is the most intimately concerned with the outcome is the forum whose law should be applied." Id. (citing In re Complaint of Bankers Trust Co., 752 F.2d 874, 882 (3d Cir. 1984)); see also Myers v. Commercial Union Assur. Co., 485 A.2d 1113, 1115-6 (Pa. 1984). With respect to Knight's claims, all of the key events took place in Florida, so Florida law applies. For the Williams' claims, the operative facts took place in Pennsylvania, so Pennsylvania law applies.

3. Knight's Manufacturing Defect Claims

Knight asserts a strict liability claim under Florida law, alleging that the VNS System medical device that was implanted in her suffered from a manufacturing defect. Under Florida law, a strict products liability action requires the plaintiff to prove that (1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury. McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1257 (11th Cir. 2002) (citing Edward M. Chadbourne, Inc. v. Vaughn, 491 So. 2d 551, 553 (Fla. 1986)).

Knight testified that approximately eight months after implantation of the VNS System, she experienced severe shocks that lasted for thirty seconds every five minutes. She was unable to speak or breathe during the shock episodes, and was forced to tape a magnet to her chest to disable the VNS System. As a result of these ongoing severe shocks, the VNS System was explanted.

After explantation, Cyberonics conducted a product analysis of the VNS System that indicated no adverse findings, other than typical wear. There were no product-related issues with the returned lead. Similarly, a product analysis on the generator determined that it delivered appropriate programmed output currents in the laboratory setting. It found that "[t]he pulse generator performed according to specifications." Cyberonics' testing showed that the device met design specifications and was functioning as designed.

Where a defendant has made a showing that the device complied with the premarket approval, as Cyberonics has here, the plaintiff must provide some evidence that the VNS System deviated from the FDA-approved standards. Knight's only argument is that she is entitled to a legal inference that the product was defective because it malfunctioned during normal operation.

See McCorvey, 298 F.3d at 1258 (citing Cassisi v. Maytag Co., 396 So. 2d 1140 (Fla. 1st Dist. Ct. App. 1981)). This argument is plainly insufficient. Avoiding federal preemption requires evidence that the medical device did not adhere to the premarket approval, and Knight failed to make such a showing.

Thus, I find that Knight has failed to demonstrate a genuine dispute of material fact as to whether her device departed from FDA-approved standards. Riegel precludes liability under such circumstances. I grant Defendant's motion for summary judgment with respect to Knight's claim of strict liability for a manufacturing defect.

4. The Williams' Manufacturing Defect Claims

To prove strict liability under Pennsylvania law, "a plaintiff has the burden of showing that the product was defective, that the defect was the proximate cause of his or her injuries and that the defect existed at the time the product left the manufacturer." Dansak v. Cameron Coca-Cola Bottling Co., 703 A.2d 489, 495 (Pa. Super. 1997) (internal quotations omitted). In cases alleging a manufacturing defect, the plaintiff may proceed on a "malfunction theory" of liability instead of providing direct evidence of the defect. Id. at 495-96. This theory allows the plaintiff to proceed by presenting "a case-in-chief evidencing the occurrence of a malfunction and eliminating abnormal use or reasonable, secondary causes for the malfunction." Id. (internal quotations omitted). The malfunction itself is circumstantial evidence of the defect. Id.

Williams testified that the VNS System had no effect on her depression and that the device eventually stopped emitting electrical pulses. Plaintiffs thus argue not that the VNS System was designed inappropriately, but that the medical device failed to function according to its design because it simply stopped working. Cyberonics, however, conducted a product

analysis of the VNS System after explantation. This analysis reported no product-related anomalies with the returned portions of the lead or the generator, aside from those associated with typical wear or the explant procedure. Testing showed that the device was "functioning as designed." Additionally, Cyberonics notes that the product did deliver appropriate electrical impulses when it was first implanted. The Williams provide no countervailing evidence that the product was not manufactured as designed. On this record, there is absolutely no reason to believe that Williams' VNS System failed to meet all of the FDA's requirements.

Without proof that the VNS System did not adhere to the premarket approval, the Williams' claim must fail. Accordingly, I grant Defendant's motion for summary judgment with respect to the Williams' claim of strict liability for a manufacturing defect.

5. Plaintiffs' Breach of Warranty Claims

The rationale relating to the strict liability claims also applies to Plaintiffs' claims for breach of implied warranty. Any state common-law claim for a breach of implied warranty is preempted because it would impose new or additional requirements on manufacturers. Riegel, 128 S.Ct. at 1009. In Riegel, the Supreme Court did not specifically address whether claims for breach of express warranty are preempted. However, Plaintiffs generally plead a "breach of warranty" without specifying whether they claim a breach of an express warranty or an implied warranty. To the extent that they do plead a warranty breach, they fail to set forth any facts demonstrating that Cyberonics made an express guarantee. Therefore, Plaintiffs' claim is restricted to one of breach of implied warranty. See Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the

court to draw the reasonable inference that the defendant is liable for the misconduct alleged."). I grant Defendant's motion for summary judgment with respect to Count II.

B. Misrepresentation (Counts III and IV)

Knight has conceded that she did not rely on any representations by Cyberonics regarding payment for services through health insurance, and consents to the dismissal of those claims. Accordingly, I dismiss Knight's claims for fraudulent and negligent representation against Cyberonics.

The Williams allege both fraudulent (Count III) and negligent misrepresentation (Count IV).

1. Fraudulent Misrepresentation (Count III)

To establish a claim for fraudulent misrepresentation, a plaintiff must show: (1) a misrepresentation, (2) a fraudulent utterance thereof, (3) an intention by the maker that the recipient will thereby be induced to act, (4) justifiable reliance by the recipient upon the misrepresentation and (5) damage to the recipient as the proximate result. Martin v. Lancaster Battery Co., 606 A.2d 444, 448 (Pa. 1992); Tunis Bros. Co. v. Ford Motor Co., 952 F.2d 715, 731 (3d Cir. 1991).

It is undisputed that Mr. Williams knew the insurance company had already denied approval for VNS therapy when he and his wife decided to proceed with the implant. It is also undisputed that Cyberonics never promised the Williams that their insurance company would cover VNS therapy. However, Plaintiffs contend that Cyberonics misled the Williams by exaggerating the likelihood of success on their appeal to the Office of Personnel Management.

Plaintiffs have failed to demonstrate that there was in fact a misrepresentation. Although Mr. Williams testified that a Cyberonics case manager told him that the Office of Personnel Management rarely denied insurance approval for the VNS System, Plaintiffs lack any evidence that could actually be used to evaluate the veracity of that statement. At best, they point to a September 11, 2006 Cyberonics press statement indicating that 1,800 patients with treatment resistant depression have begun treatment with VNS therapy, while insurance companies denied payments for approximately 7,000 patients. This release, published nearly a year after Williams' implantation, provides minimal insight about the likelihood of insurance coverage when Mr. Williams actually spoke to the Cyberonics case manager. Moreover, the release notes that nearly 250 different payer plans have granted approval for the VNS System. It provides no information on whether the Office of Personnel Management typically approves or denies coverage for the device.

Plaintiffs also look for support in a September 6, 2006 letter from Public Citizen urging the Center for Medicare and Medicaid Services to deny Medicare reimbursement for the VNS System. The letter is similarly unhelpful. Although it notes that several Local Coverage Determinations declined to provide Medicare reimbursement for the VNS System, it provides no information about Mrs. Williams' insurance company, or whether the Office of Personnel Management would approve coverage for the device.

Plaintiffs have failed to provide any evidence showing that Cyberonics' statements that the Office of Personnel Management rarely denied coverage are anything other than true. As Mr. Williams testified, Cyberonics never promised him that his wife's treatment would be covered. Mr. Williams understood that coverage for the VNS System was entirely at the Office of

Personnel Management's discretion. The fact that this one claim was denied cannot be used as generalized proof that the Office of Personnel Management frequently denied coverage, and certainly cannot be used to show that Cyberonics should have known about those instances.

Accordingly, Defendants' motion for summary judgment on Count III is granted.

2. Negligent Misrepresentation (Count IV)

To succeed on a claim for negligent misrepresentation, a plaintiff must prove: (1) a misrepresentation of a material fact, (2) made under circumstances in which the misrepresenter ought to have known its falsity, (3) with an intent to induce another to act on it, and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation. Bortz v. Noon, 729 A.2d 555, 561 (Pa. 1999).

As with the claim for fraudulent misrepresentation, Plaintiffs have failed to provide any evidence sufficient to demonstrate a misrepresentation of material fact. Therefore, I grant Defendant's Motion for Summary Judgment as to Count IV.

s/Anita B. Brody

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ANITA B. BRODY, J.

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